

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

comparison of short-term outcomes between amniotic membrane and conventional dressing in skin graft Donor site in patients hospitalized in the burn ward of Imam Khomeini Hospital of Urmia in 2019

Protocol summary

Study aim

Comparison of short-term outcome of amniotic membrane dressing versus routine dressing in donor graft site in burn patients in Urmia Imam Khomeini Hospital in 2019

Design

A quasi-experimental trial without a randomization process in which 26 donor sites received different dressings on both sides of the body.

Settings and conduct

This clinical trial study will be carried out in the burn ward of Imam Khomeini Hospital of Urmia in 2019. The patient in intervention group will be treated with amniotic membrane dressing (left side of the patient) and topical antimicrobial dressing (right side of the patient). Patients in control group on the right side will be treated with nitrofurazone-impregnated gauze and 2 g of ointment for each percent of the graft site, and the left side will be dressed by amniotic membrane. The desired variables for all patients will be extracted through a questionnaire designed for this purpose.

Participants/Inclusion and exclusion criteria

Exclusion criteria: patients with underlying diseases (diabetes, Renal failure, hepatitis, immune deficiency and cardiovascular disease) ;Inclusion criteria: All persons aged between 1 to 66 years

Intervention groups

intervention group: amniotic membrane dressing in the left side of patient, control group:nitrofurazone dressing in the right side of the patient.

Main outcome variables

scar status and wound epithelization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190614043889N1**

Registration date: **2020-02-13, 1398/11/24**

Registration timing: **retrospective**

Last update: **2020-02-13, 1398/11/24**

Update count: **0**

Registration date

2020-02-13, 1398/11/24

Registrant information

Name

jafar kazemzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 9538

Email address

jafarkazemzade48@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-04, 1398/03/14

Expected recruitment end date

2019-12-05, 1398/09/14

Actual recruitment start date

2019-06-04, 1398/03/14

Actual recruitment end date

2020-01-04, 1398/10/14

Trial completion date

2020-01-04, 1398/10/14

Scientific title

comparison of short-term outcomes between amniotic membrane and conventional dressing in skin graft Donor

site in patients hospitalized in the burn ward of Imam Khomeini Hospital of Urmia in 2019

Public title

Comparison of between amniotic membrane and conventional dressing outcomes in burned skin graft Donor site

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient age 1-66 years old Patient accept biologic dressing Burns require skin grafts regardless of burning percent

Exclusion criteria:

have underlying disease such as diabetes mellitus renal failure hepatitis vascular insufficiency and heart disease patient have other trauma

Age

From **1 year** old to **66 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

More than 1 sample in each individual

Number of samples in each individual: **2**

comparison of graft donor site in left and right side

Actual sample size reached: **26**

More than 1 sample in each individual

Actual sample size in each individual: **2**

comparison of graft donor site in left and right side

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Research Commity Of Urmia Medical university

Street address

ershad ave emam khomeini hospital born ward

City

Urmia

Province

West Azarbaijan

Postal code

5715718516

Approval date

2019-06-02, 1398/03/12

Ethics committee reference number

ir.umsu.rec.1398.081

Health conditions studied

1

Description of health condition studied

Burn. Donor Graft Side

ICD-10 code

T30.0

ICD-10 code description

Burn of unspecified body region, unspecified degree

Primary outcomes

1

Description

Epithelialization and scar in donor graft site

Timepoint

effect of Biologic dressing in donor graft site on days 7, 14 and 30

Method of measurement

Information Gathering Form

Secondary outcomes

1

Description

Local infection rate

Timepoint

over a period of one month

Method of measurement

observed local infection

2

Description

Amount of pain

Timepoint

during a period of one month

Method of measurement

Visual Analogue Scale

3

Description

Patients' rate of co-operation in dressing replacement

Timepoint

during a period of one month

Method of measurement

observation

4

Description

Duration of recovery time

Timepoint

over a period of one month

Method of measurement

week

5

Description

itching rate

Timepoint

during a period of one month

Method of measurement

to measure with Nominal Scale (yes/no)

Intervention groups

1

Description

Intervention group: the patient's left side will be dressed biologically with amniotic membrane.

Category

Treatment - Surgery

2

Description

Control group: The right side of the patient is dressed with Nitrofurazone impregnated gas and 2 grams of ointment will be used for each percentage of the graft site

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Burn Center of Imam Khomeini Hospital in Urmia

Full name of responsible person

Dr. Jafat Kazemzadeh

Street address

Ershad ave Emam Khomeini hospital

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Postal code

5715718516

Phone

+98 44 3198 8111

Email

jafarkazemzade48@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Jafar Kazemzade

Street address

Ershad ave emam khomeini hospital

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Jafar Kazemzadeh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Jafar Kazemzade

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data related to the primary and secondary outcomes will be provided to clinical researchers in full detail after unidentifiable individuals and articles are published.

When the data will become available and for how long

Up to 6 months after publishing results

To whom data/document is available

Researchers, Ethics Committee

Under which criteria data/document could be used

cite of clinical results in other similar researches and collaborating with other large multi center clinical trials with approval ethical committee and IRCT center.

From where data/document is obtainable

The results are available in the form of articles and seminars to applicants and can be contacted by Dr. Jafar Kazemzadeh, Imam Hospital Burn Unit. Urmia.Imam Hospital. Burn Section.Jafar Kazemzadeh. Contact No. 098 44 33459539

What processes are involved for a request to access data/document

The applicant can access the results of the study by written request or by contacting the center within a maximum of 10 working days.

Comments